

§ 26.1607

conditions recommended pursuant to § 26.1603(d).

[78 FR 10545, Feb. 14, 2013]

§ 26.1607 Human Studies Review Board review of completed human research.

In commenting on reports of completed research submitted to it by EPA, the Human Studies Review Board must consider the scientific merits and ethical aspects of the completed research, and must apply the appropriate standards in subpart Q of this part.

[78 FR 10545, Feb. 14, 2013]

Subpart Q—Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1701 To what does this subpart apply?

(a) For decisions under FIFRA (7 U.S.C. 136–136y) or section 408 of FFDCA (21 U.S.C. 346a), this subpart applies to research involving intentional exposure of human subjects to any substance.

(b) For decisions under any regulatory statute administered by EPA other than those statutes designated in paragraph (a) of this section, this subpart applies to research involving intentional exposure of human subjects to a pesticide.

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§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 also apply to this subpart.

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§ 26.1703 Prohibitions applying to all research subject to this subpart.

(a) Prohibition of reliance on scientifically invalid research. EPA must not rely on data from research subject to this subpart unless EPA determines that the data are relevant to a scientific or policy question important for EPA decisionmaking, that the data were derived in a manner that makes them scientifically valid and reliable,

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and that it is appropriate to use the data for the purpose proposed by EPA. In making such determinations, EPA must consider:

(1) Whether the research was designed and conducted in accordance with appropriate scientific standards and practices prevailing at the time the research was conducted.

(2) The extent to which the research subjects are representative of the populations for the endpoint or endpoints in question.

(3) The statistical power of the data to support the scientific conclusion EPA intends to draw from the data.

(4) In a study that reports only a No Observed Effect Level (NOEL) or a No Observed Adverse Effect Level (NOAEL), whether a dose level in the study gave rise to a biological effect, thereby demonstrating that the study had adequate sensitivity to detect an effect of interest.

(b) Prohibition of reliance on research subject to this subpart involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children. Except as provided in § 26.1706, EPA must not rely on data from any research subject to this subpart involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

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§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults.

(a) This section applies to research subject to this subpart that is not subject to § 26.1705.

(b) Except as provided in § 26.1706, EPA must not rely on data from any research subject to this section if there is clear and convincing evidence that:

(1) The conduct of the research was fundamentally unethical (*e.g.*, the research was intended to seriously harm participants or failed to obtain informed consent); or

(2) The conduct of the research was deficient relative to the ethical standards prevailing at the time the research was conducted in a way that placed participants at increased risk of harm (based on knowledge available at